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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,368	04/20/2006	Frederick R. Kettinger	525.1089-PCT-US	5602
20311 7590 09/05/2008 LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016				
EXAMINER				
VO, TUYEN KIM				
ART UNIT		PAPER NUMBER		
2887				
MAIL DATE		DELIVERY MODE		
09/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,368

Applicant(s)

KETTINGER ET AL.

Examiner

Tuyen Kim Vo

Art Unit

2887

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment

1. This Office Action is responsive to the Amendment filed on 06/13/2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8, 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus et al. (US 6,543,692 B1, hereinafter "Nellhaus") in view of Sullivan et al. (US 5,992,742, hereinafter "Sullivan").

Re claims 1, 14 and 17, Nellhaus, as shown in figure 10, teaches a system and method of a solid form drug (72) comprising a core portion (75) having sufficiently low friability; a readable printed or etched marking (data matrix 82) on the surface of the core, the marking providing identification/authentication of the oral dosage form. See column 4, lines 26-50.

However, Nellhaus fails to disclose or suggest the readable printed or etched marking is a covert readable printed or etched marking.

Sullivan teaches a marking code on the pill which is invisible. See column 8, lines 55-67 and column 12, lines 38-62. In addition, Sullivan further teaches a barcode

is printed on a label of a pill, which has a code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto. See column 11, line 36 to column 12, line 43.

In view of Sullivan's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the readable printed (data matrix 82) of Nellhaus with an invisible code (covert readable printed) as taught by Sullivan so that the data cannot be seen or read by a human. Such modification would also help counter unauthorized or unintentional exchanges of pills in a container. See Sullivan: column 8, lines 55-67.

Re claim 3, Nellhaus further teaches the printed or etched marking is a barcode (data matrix 82). See column 4, lines 51-54.

Re claim 4, Nellhaus further teaches the barcode is a 2D data matrix barcode. See column 1, lines 13-18.

Re claim 5, Sullivan further teaches the film coat contains a colorant (the gelatin film has slightly yellow color, see Webster's II, new college dictionary, Houghton Mifflin Company, Boston, New York, Copyright © 1995, page 464). See column 11, lines 36-38.

Re claim 6, Nellhaus further teaches the marking is readable with a barcode scanner (a pen, figure 13). See column 5, line 66 to column 6, line 2.

Re claim 7, Nellhaus further teaches the marking is readable with detection equipment which does not depend upon visible light waves. See column 2, lines 29-35 and column 3, lines 15-19.

Re claims 8 and 20, Nellhaus further teaches an overt marking thereon (hybrid data matrix symbol 90, figure 12). See column 5, lines 49-57.

Re claims 11 and 18, Nellhaus further teaches the surface of the core further comprises a debossed region (icon 75, figure 10, which serves as a debossed region) into which the printed or etched marking is place. See column 4, lines 44-47.

Re claim 12, Nellhaus further teaches the debossed region has a substantially horizontal plane with respect to the center of the core. See figure 10; column 4, line 44-47.

Re claims 13, 15, 16 and 21, Nellhaus further teaches the core has an ink coating applied to a portion thereof to the marking being applied thereto. See column 3, lines 10-22.

Re claim 22, the teachings of Nellhaus as modified by Sullivan have been discussed above. In addition, Sullivan further teaches the pad printing is applied using an ingestible and pharmaceutically ink. See column 12, lines 18-28.

Re claims 23 and 24, the teachings of Nellhaus as modified by Sullivan have been discussed above. Nellhaus also teaches the different sizes (concentrating) of the marking such as 4x4, 5x5,...etc..., see column 1, lines 25-62. Therefore, to provide the

marking with the range of about 2 to about 5 ppm is obvious from the different sizes of Nellhaus since it is just a variation of sizing.

In addition, Sullivan teaches a film (a protein based film such as keratin or gelatin film) coating on the code-receiving layer. See column 11, line 36 to column 12, line 43.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus to employ the film coated on the core portion (code-receiving layer) as taught by Sullivan with the amount as suggested by Nellhaus so that to easily adhere to the pill which marking can be easily applied thereon. See column 11, lines 36-55 of Sullivan.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan as applied to claim 1 above, and further in view of Siegel (US 2004/0166063 A1).

Re claim 9, the teachings of Nellhaus as modified by Sullivan have been discussed above. However, Nellhaus as modified by Sullivan fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable by aroma.

Siegel teaches marking the pharmaceutical product (pills) with a covert scent profile which is detectable by aroma. See [0102] and [0103].

In view of Siegel's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Sullivan by providing the marking which is detectable by scent as taught by

Siegel to the cover marking of Nellhau as modified by Sullivan in order to prevent counterfeiting of the aromas and to identify the pharmaceutical formulation/products.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan as applied to claims 1/8 above, and further in view of Johnson et al. (US 6,171,618 B1, hereinafter "Johnson").

Re claim 10, the teachings of Nellhaus as modified by Sullivan have been discussed above. However, Nellhaus as modified by Sullivan fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable using HPLC.

Johnson teaches a HPLC system uses to monitor or detect the dosage. See column 14, lines 3-29.

In view of Johnson's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the covert marking of Nellhaus as modified by Sullivan so that it can be detected by HPLC as taught by Johnson since HPLC is used to monitor or detect the chemical using UV detecting.

Response to Arguments

6. Applicant's arguments filed 06/13/2008 have been fully considered but they are not persuasive.

Applicant traverses to the rejection by mainly arguing that Sullivan does not teach the "core is film coated prior to said printed or etched marking being applied thereto" as recited in claims 1 and 14.

However, as taught by Sullivan at column 11, lines 36-39, the code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto. Moreover, film coating doesn't have to involve coating the whole body of the core/substrate and especially, it is noted that such limitation (coating the whole substrate) is not in the claim.

Base on the above rationale, it is believed that the rejection to claims 1, 3-18 and 20-24 are proper and therefor, the rejections to the claims are still maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuyen Kim Vo whose telephone number is (571)270-

1657. The examiner can normally be reached on Monday - Friday, 7:30a.m. - 5:00p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven S. Paik can be reached on (571) 272-2404. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tuyen Kim Vo/
Examiner, Art Unit 2887

/Uyen-Chau N. Le/
Primary Examiner, Art Unit 2887